K010455

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VIII. SAFETY AND EFFECTIVENESS SUMMARY

The STA®-Rotachrom® Heparin kit is intended for use on STA® analyzers (K942117) for the quantitative determination of plasma levels of unfractionated heparins (UFH) and low molecular weight heparins (LMWH) by the measurement of their anti-Factor Xa (anti-Xa) activity using an amidolytic method.

The method proposed by STA®-Rotachrom® Heparin is a one-step procedure: the test plasma is first mixed with a chromogenic substrate that is specific for Factor Xa; then, an excess amount of Factor Xa is added; competition between the Factor Xa and heparin-AT III-complex in the test plasma for the chromogenic substrate takes place. After the required time duration for equilibrium to reach, the amount of para-nitroaniline (pNA) that is released is measured spectrophotometrically at 405-nm. The intensity of the released pNA, as reflected by the optical density (OD) measured at 405-nm, is inversely proportional to the heparin level initially present in the test plasma.

By performing the test on known calibrators, either UFH or LMWH, on an STA® analyzer a calibration line is obtained. The heparin levels of patient plasmas are derived from this calibration line by the STA® analyzer.

The STA®-Rotachrom® Heparin kit is available in two sizes: STA®-Rotachrom® Heparin [4] providing reagents in 4-ml vials; STA®-Rotachrom® Heparin [8] providing reagents in 8-ml vials.

Reagents in intact kits remain stable for 24 months after the date of manufacture, when stored at 2°-8°C. Reconstituted reagents are stable for 7 days on board STA® analyzers.

Substantial equivalence has been established for the STA®-Rotachrom® Heparin with the predicate device Coamatic® Heparin from Chomogenix-Instrumentation Laboratory.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN - 7 2001

Andrew Loc B. Le, Ph.D.
Director for Regulatory Affairs and Quality Assurance
Diagnostica Stago, Inc.
Five Century Drive
Parsippany, New Jersey 07054

Re: K010455
Trade Name: Diagnostica Stago STA®-Rotachrom® Heparin Test Kit
Regulation Number: 21 CFR 864.7525
Regulatory Class: II
Product Code: KFF
Dated: April 23, 2001
Received: April 24, 2001

Dear Dr. Le:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment A

Supplement to 510(k) Number : ~~K943515~~ K010455

Device Name: STA® Rotachrom® Heparin Test Kit

Indications for Use:

The Rotachrom® Heparin test kit was originally cleared under K943515 for the assays of unfractionated heparin (UFH) only. Subsequently, the same kit was provided with bar-coded reagent labels for assays of UFH performed on the fully automatic STA® analyzers (K942117), and the STA® logo was added to the kit labellings which became STA® Rotachrom® Heparin.

This 510(k) supplement provides data for STA® Rotachrom® Heparin which can now be used for assays of both UFH and low molecular weight heparins (LMWH) on STA® analyzers.

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K010455

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

(Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)